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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,229

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Elizabeth Rajan

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EXAMINER

TREYGER, ILYA Y

ART UNIT

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12/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,229	Applicant(s) RAJAN ET AL.	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/2009 has been entered.
2. Claims 1 and 8 are amended.
3. Claims 5-7 and 9 are canceled.
4. Rejection of claim 7 under 35 U.S.C. 112, second paragraph has been withdrawn based on cancellation of the claim.
5. Claims 1-4, 8 and 10-13 are examined on the merits.

Response to Arguments

6. Applicant's arguments filed 09/22/2009 have been fully considered but they are not persuasive.

With regard to claim 1, Applicants argue that Rockey does not disclose the claimed invention because the expandable balloons described by Rockey are not described as asymmetrical toroidal shaped.

However, the limitation of "asymmetrical toroidal shape" renders claim indefinite, since the toroid is a symmetrical figure by the definition (See The American Heritage® Dictionary of the English Language, Fourth Edition).

Art Unit: 3761

In addition, since expandable toroidal inflatable balloon 50 of Rockey is disclosed as made of flexible material, it necessarily takes the asymmetric form during the use as being affected by surrounding tissues comprising turgor.

7. Applicants further argue that the combination of references is improper because Stack does not describe an esophageal extension.

However, the esophageal extension A is clearly depicted on the Fig. 17C of Stack.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4, 8 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is indefinite term of the “asymmetric toroidal chamber”, since in accordance with the definition, toroid is a surface generated by a closed curve rotating about, but not intersecting or containing, an axis in its own plane, that reads on is symmetric by the definition.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3761

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-4, 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rockey (US 4,763,653) in view of Stack et al. (US 2003/0199991).

14. In Re claim 1, Rockey discloses a sleeve unit insertable in a natural body vessel (Abstract, lines 2, 3) capable of being used as a gastro-intestinal device (Col. 2, lines6-8), comprising:

a sleeve 51 (Fig. 9) that is a gastric bypass having an inlet A (Fig. 9) and outlet B (Fig. 9); and

an expandable inflatable balloon 50 (Fig. 9) attached to the gastric bypass (Col. 5, lines 64-68) fully capable of taking the asymmetric form, since it is made of flexible material.

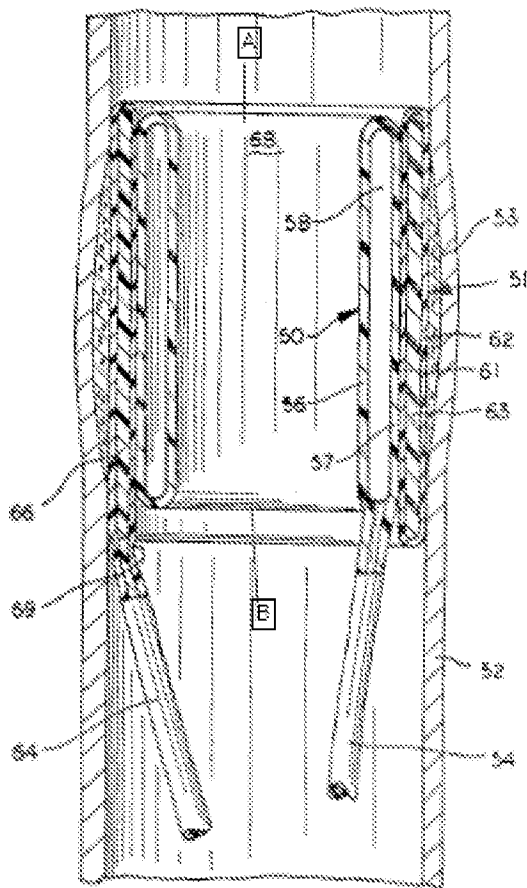
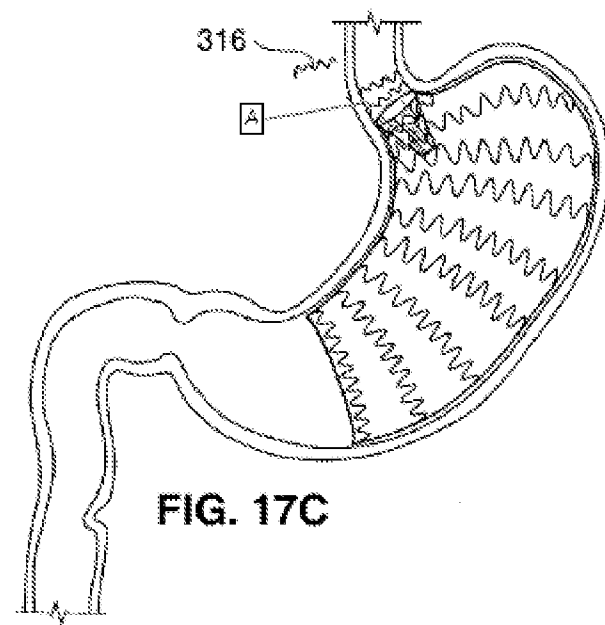
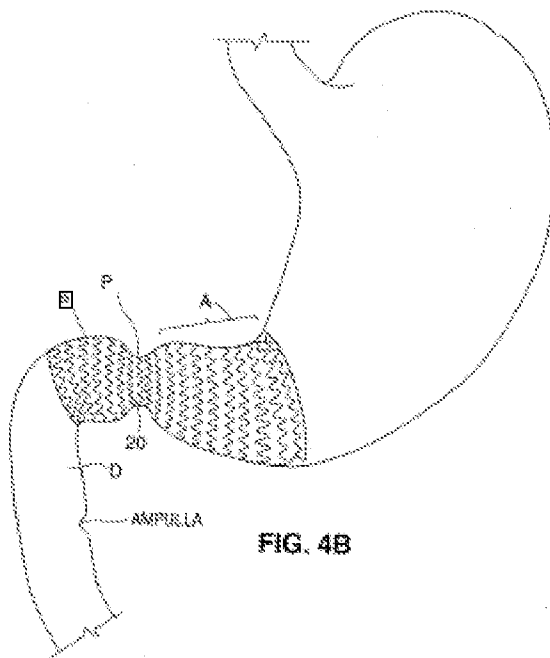


FIG. 9

Rockey does not expressly disclose the gastric bypass comprising a permeable material; an esophageal extension; and a bowel extension.

Stack teaches a gastric bypass comprising material that allows the substances to pass from the reservoirs into the surrounding tissue (page 2, [0039], lines 9-11); an esophageal extension A (Fig. 17C); and a bowel extension B (Fig. 4B).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Rockey with the permeable material, an esophageal extension and a bowel extension, as taught by Stack in order to utilize the bypass of the conventionally known type.

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a).

Art Unit: 3761

Ex Parte Smith, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

In regard to limitation “an esophageal extension comprising one or more flaps”, Rockey in view of Stack do not expressly disclose the one-way flap valve located in the esophageal extension of the device.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the esophageal extension of the device with the one-way valve, since the constrictio phrenica (natural gastroesophageal flap valve) has been affected by the device, wherein it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the one-way valve in the form of flap valve, since it was known in the art that a valve having a hinged flap permitting flow only in the direction in which the flap opens (See *Dictionary.com Unabridged Based on the Random House Dictionary*, © Random House, Inc. 2009) (**MPEP 2144.03 (A-E)**).

15. In Re claims 2 and 8, Rockey discloses the gastric bypass comprising the flaccid gastric bag, since the sleeve (sheath) is disclosed as formed of flexible material (Col. 3, line 33).

Art Unit: 3761

16. In Re claims 3 and 10, Rockey discloses the invention discussed above, but does not expressly disclose the device having ribs facilitating collapse of the tube in the absence of compressive forces.

Stack teaches the gastric bypass comprising radially extending tabs 13 (Fig. 16B) that are ribs (claim 10) facilitating collapse of the tube in the absence of compressive forces (page 3, [0045], lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rockey with the tabs, as taught by Stack in order to facilitate collapse of the tube (page 3, [0045], line 2).

17. In Re claims 4 and 13, Rockey discloses the invention discussed above, but does not expressly disclose the device formed of a polymeric sleeve with nitinol struts embedded in the sleeve material.

Stack teaches the device formed of a polymeric sleeve with nitinol struts embedded in the sleeve material (See page 4, [0060], lines 8-10), wherein the wire is disposed helically (claim 13).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rockey with the nitinol struts, as taught by Stack in order to provide the device with the additional rigidity.

18. In Re claims 11 and 12, Rockey in view of Stack disclose the invention discussed above, as applied to claim 3, but do not expressly disclose the particular disposition character of the ribs.

Art Unit: 3761

Since Applicant did not state that such disposition character serves any specific purpose or performs any specific function other than the function disclosed in Stack, i.e. facilitating collapse of the tube, such disposition character is the matter of the obvious design choice, and therefore it would have been obvious to those skilled in the art at the time the invention was made to dispose ribs helically or longitudinally as an obvious design choice, and as such it does not impact the patentability of claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/590,229

Page 10

Art Unit: 3761

/Ilya Y Treyger/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761